UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

DETROIT MEDICAL CENTER, on behalf of itself and all others similarly situated, Plaintiff, vs. CSL LIMITED, CSL BEHRING LLC, and BAXTER INTERNATIONAL INC., Defendants.	No. **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

CLASS ACTION COMPLAINT

Plaintiff Detroit Medical Center ("Plaintiff"), on behalf of itself and all others similarly situated, brings this action for treble damages, injunctive relief and costs of suit under the antitrust laws of the United States against CSL Limited, CSL Behring LLC, and Baxter International, Inc. ("Defendants"), and alleges as follows:

BACKGROUND

1. Plasma is the watery liquid in which blood cells are suspended. It is derived from humans during blood and/or plasma donations. The type of blood plasma obtained as a byproduct of whole blood collected during blood donations is typically referred to as "recovered plasma" and comes from unpaid volunteers. Plasma collected from plasma donations is commonly referred to as "source plasma" and comes from paid donors.

2. Plasma-Derivative Protein Therapies are plasma-based products used to treat patients suffering from serious illnesses such as bleeding disorders and immune deficiencies.

The Plasma-Derivative Protein Therapies involved in the unlawful conduct alleged herein are Immune globulin ("Ig", "IGIV" or "IVIG") and Albumin.

3. Blood plasma therapies are unique among pharmaceuticals and biologics because their production begins with a biological starting material – human plasma – instead of a chemical or synthetic, which is the starting material for the majority of pharmaceuticals. Human plasma is abundant in a number of proteins, including albumin, clotting factors, immunoglobins, and alpha-1 proteinase inhibitors. These proteins are utilized to make therapies that treat rare, chronic diseases such as hemophilia, primary immunodeficiencies, and acute conditions.

4. The ability to produce high-quality blood plasma-derived therapies that are safe for consumers depends in part on the willingness of people to donate plasma, including by paid donations. The process of donating blood plasma is a long and tedious one. The first donation can take up to three hours of a donor's time, and involves a series of screenings, donor education, and the actual donation process itself. After the first donation, subsequent donations can take up to two hours. It is mandatory that the first two donations test negative for transmissible diseases before the first donation can be used.

5. The production of blood plasma-derived therapies is done through a process called fractionation. The process is unique to plasma-derived therapies. In this process, the plasma is pooled, purified, and processed to extract specific plasma proteins that have a proven health benefit. Therapeutic proteins are then extracted from a plasma production pool of multiple donations in a specific order. These proteins are separated using a linked series of steps with varying conditions of temperature, pH, and ethanol concentration, among others. The number of proteins that are extracted from this pool is known as the yield. Due to the

complexity of the fractionation process, the time between donation and final product release can be as long as nine months.

The Product Industry

6. The blood plasma-derived product industry is valued at $14 billion globally. The United States accounts for approximately 70 percent of the world's supply of plasma.

7. In terms of demand, North America accounts for 40 percent of the product market, with Europe constituting 32 percent and Asia 19 percent.

8. Every year, tens of thousands of people in the United States require Plasma-Derivative Protein Therapies to treat serious illnesses and life-threatening illnesses including clotting disorders, liver disease, and hemophilia.

9. The annual cost for Plasma-Derivative Protein Therapies can exceed $90,000 per patient in some cases.

10. Plasma-Derivative Protein Therapies sold in the United States must be made from plasma collected in the United States. Defendants are the primary developers, manufacturers and sellers of Plasma-Derivative Protein Therapies in the United States. Defendants manufacture and sell a substantial majority of the Plasma-Derivative Protein Therapies sold in the United States.

11. Defendants collectively sell billions of dollars worth of Plasma-Derivative Protein Therapies every year in the United States.

12. During the Class Period (defined below), Defendants engaged in a conspiracy to artificially fix, raise, maintain or stabilize the prices of Plasma-Derivative Protein Therapies in the United States by agreeing to restrict the output of Plasma-Derivative Protein Therapies. As a result of this illegal conspiracy, Defendants were able to charge supra-competitive prices for

Plasma-Derivative Protein Therapies sold in the United States, thereby injuring Plaintiff and members of the Class.

JURISDICTION AND VENUE

13. This action arises under Section 1 of the Sherman Act and Sections 4 and 16 of the Clayton Act (15 U.S.C. §§ 1, 15 and 26).

14. This Court has jurisdiction under Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26, and 28 U.S.C. §§ 1331 and 1337.

15. Venue is proper in this District pursuant to sections 4 and 12 of the Clayton Act, §§ 15(a) and 22, and 28 U.S.C. § 1391(b), (c) and (d). Defendants are found and transact business in the District and/or the claims arose at least in part in the District. Defendants regularly and continuously conduct business in interstate and foreign commerce between and among the United States and foreign countries. The interstate trade and commerce relevant to this action has been carried out, in part, within the District.

PARTIES

16. Plaintiff Detroit Medical Center is a Michigan not-for-profit corporation with its principal place of business in Detroit, Michigan. During the Class Period, Plaintiff purchased Plasma-Derivative Protein Therapies Ig and albumin in the United States directly from one or more of the Defendants and was injured as a result of Defendants' unlawful conduct.

17. Defendant CSL Limited is an Australian corporation with its principal place of business at 45 Poplar Road, Parkville, Victoria, 3052, Australia. CSL Limited is the second largest supplier of Plasma-Derivative Protein Therapies in the world. It is a vertically-integrated company, with a large network of plasma collection facilities in addition to drug manufacturing facilities. CSL Limited had worldwide sales of approximately $2.4 billion for its 2008 fiscal year.

18. CSL Behring LLC is CSL Limited's wholly-owned subsidiary headquartered at 1020 First Avenue, King of Prussia, Pennsylvania, 19406. CSL Behring owns and operates more than 70 plasma collection facilities in the United States and Germany, and three plasma manufacturing centers. CSL Behring had sales revenue of about $1.8 billion for its 2008 fiscal year.

19. Defendants CSL Limited and CSL Behring are collectively referred to herein as "CSL."

20. Defendant Baxter International, Inc. ("Baxter") is a Delaware corporation headquartered at One Baxter Parkway, Deerfield, Illinois, 60015. Baxter is the leading manufacturer of Plasma-Derivative Protein Therapies in the world, as well as the largest producer of such products in the United States. Baxter's BioScience division is responsible for manufacturing and selling its plasma-based protein products. Baxter had 2008 revenues of over $12 billion, with approximately 20% of sales coming from plasma products.

CO-CONSPIRATORS

21. Various other companies and individuals not named as Defendants in this Complaint participated as co-conspirators in the acts complained of, and performed acts and made statements in furtherance of the unlawful conduct. Plaintiff reserves the right to name subsequently some or all of these persons as defendants.

22. Whenever in this Complaint reference is made to any act, deed, or transaction of any corporation, the allegation means that the corporation engaged in the act, deed, or transaction by or through its officers, directors, agents, employees, or representatives while they were actively engaged in the management, direction, control, or transaction of the corporation's business or affairs.

CLASS ACTION ALLEGATIONS

23. Plaintiff brings this action as a class action under Rules 23(a), (b)(2) and 23(b)(3) of the Federal Rules of Civil Procedure, on behalf of itself and others similarly situated. The "Class" is defined as:

> All persons or entities who purchased Plasma-Derivative Protein Therapies Ig or albumin directly from one or more of the Defendants or their co-conspirators in the United States (the "Class"), at any time from at least May 11, 2004 through the present (the "Class Period"). Excluded from the Class are Defendants, subsidiaries or affiliates of Defendants, Defendants' co-conspirators, whether or not named as a Defendant in this Complaint, and government entities.

24. The Class is so numerous that joinder of all members is impracticable. Due to the nature of the trade or the commerce involved, Plaintiff believes that the members of the Class are geographically dispersed throughout the United States, and that joinder of all Class members would be impracticable. While the exact number of Class members is unknown to Plaintiff at this time, Plaintiff believes that there are at least hundreds of members of the Class and that their identities can be learned from Defendants' and their co-conspirators' books and records.

25. Plaintiff's claims are typical of the claims of the other members of the Class. Plaintiff and members of the Class purchased Plasma-Derivative Protein Therapies during the Class Period at artificially maintained, non-competitive prices, resulting from the unlawful actions of Defendants and their co-conspirators. Plaintiff and members of the Class have sustained damage in that they paid inflated prices for Plasma-Derivative Protein Therapies during the Class Period due to Defendants' conduct in violation of federal law as set forth below.

26. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class action and antitrust litigation.

27. Common questions of law and fact exist as to all members of the Class, which predominate over any questions affecting solely individual members of the Class. Among the questions of law and fact common to the Class are:

(a) Whether Defendants conspired with each other and their co-conspirators to raise, fix, maintain or stabilize the price of Plasma-Derivative Protein Therapies in the United States by restricting output of Plasma-Derivative Protein Therapies;

(b) Whether Defendants undertook actions to conceal their unlawful conspiracy; and

(c) Whether Defendants' conduct violated the relevant federal antitrust laws and caused injury to the business and property of Plaintiff and the members of the Class and, if so, the proper measure of damages.

28. A class action is superior to other available methods for the fair and efficient adjudication of this controversy because joinder of all Class members is impracticable. The prosecution of separate actions by individual members of the Class would impose heavy burdens upon the courts and Defendants, and would create a risk of inconsistent or varying adjudications of the questions of law and fact common to the Class. A class action, on the other hand, would achieve substantial economies of time, effort and expense, and would assure uniformity of decision as to persons similarly situated without sacrificing procedural fairness or bringing about other undesirable results.

29. The interest of members of the Class in individually controlling the prosecution of separate actions is theoretical rather than practical. The Class has a high degree of cohesion, and prosecution of the action through representatives would be unobjectionable. The amounts at stake for Class members, while substantial in the aggregate, are not great enough individually to

enable them to maintain separate suits against Defendants. Plaintiff does not anticipate any difficulty in the management of this action as a class action.

INTERSTATE TRADE AND COMMERCE

30. Throughout the Class Period, there has been a continuous and uninterrupted flow of transactions in and shipments of Plasma-Derivative Protein Therapies in interstate commerce throughout the United States.

31. The unlawful activities of Defendants and their co-conspirators have been within the flow of, and have had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

THE PLASMA-DERIVATIVE PROTEIN THERAPIES MARKET

32. Defendants are manufacturers of Ig and Albumin, which are plasma-based therapies used to treat patients suffering from numerous bleeding disorders, immune deficiencies and other serious diseases.

33. Ig is a widely used drug that can be administered intravenously ("IVIG" or "IGIV") or subcutaneously ("SCIG"). IVIG, the more predominant form, has over 20 FDA-approved indications, and as many as 150 off-label uses. The most common uses involve the treatment of Primary Immunodeficiency Diseases and neurological conditions – *e.g.,* Guillain-Barre Syndrome and chronic inflammatory demyelinating polyneuropathy.

34. Albumin is used as a blood volume expander, to prime heart valves during surgery, and to treat liver disease.

35. The manufacturing process for producing Plasma-Derivative Protein Therapies ranges from seven months to one year. It involves: (1) plasma collection; (2) plasma testing; (3) fractionation (*i.e.*, precipitation of solids by manipulation of solution pH, temperature, etc.); (4) finishing or purification; (5) quality control; and (6) lot release.

36. The manufacturing process is highly regulated because plasma products run the risk of containing and transmitting infections. Regulators include the U.S. Food and Drug Administration ("FDA"), state regulatory agencies and the Plasma Protein Therapeutics Association ("PPTA"), an industry self-regulatory body.

37. The FDA must approve plasma collection centers and the plants at which Plasma-Derivative Protein Therapies are made, as well as the therapies themselves.

38. Plasma is a very expensive raw material, representing between 40 and 70% of the cost of Plasma-Derivative Protein Therapies.

39. As further set forth below, the market has substantially consolidated over the past two decades. In 1990, there were thirteen Plasma-Derivative Protein Therapy manufacturers. In 2003, the number of Plasma-Derivative Protein Therapy manufacturers was reduced to nine. Today, there are only five: CSL, Baxter, Talecris Biotherapeutics Holdings Corporation ("Talecris"), Grifols, S.A. ("Grifols"), and Octapharma AG ("Octapharma").

40. The Federal Trade Commission ("FTC") has determined that the Plasma-Derivative Protein Therapies market operates as a "tight oligopoly."

41. The U.S. Department of Health and Human Services ("HHS") issued a report on the IGIV market in February 2007 entitled *Analysis of Supply, Distribution, Demand, and Access Issues Associated with Immune Globulin Intravenous (IGIV)* ("HHS Report"). One of its key findings was that Ig "manufacturing is a tight oligopoly in which the leading three manufacturers [CSL, Talecris and Baxter] . . . have a combined market share of around 85%."

42. During the Class Period, demand for Plasma-Derivative Protein Therapies has exceeded supply.

43. According to the HHS Report, demand for IGIV has risen sharply over the last decade. The HHS Report found that "[t]he existence of a secondary market with high IGIV prices combined with a manufacturer instituted allocation system for IGIV are symptomatic of a market in which demand exceeds supply."

44. Purchasers of Plasma-Derivative Protein Therapies will pay high prices if necessary to make treatment available to critically ill patients. As a result, small changes in production levels cause dramatic swings in prices for products, and producers stand to increase profits greatly by controlling output relative to demand.

45. Control of supply is critical to preventing price competition. Limiting the supply of Plasma-Derivative Protein Therapies serves to raise prices.

46. Prices for Plasma-Derivative Protein Therapies have increased during the class period.

Relevant Product Markets

Ig

47. Ig is a widely used drug that can be administered intravenously ("IVIG" or "IGIV") or subcutaneously ("SCIG"). IVIG, the more predominant form, has over 20 FDA-approved indications, and as many as 150 off-label uses. Ig products are antibody-rich plasma therapies that long have been used in the treatment of primary immune deficiencies (to provide antibodies a patient is unable to make) and certain autoimmune disorders where it is believed to act as an immune modulator. In addition, physicians frequently prescribe Ig for a wide variety of diseases, although these uses are not described in the product's labeling and differ from those tested in clinical studies and approved by the FDA or other regulatory agencies in other

countries. These unapproved, or "off-label," uses constitute the preferred standard of care or treatment of last resort for many patients in varied circumstances.

48. Ig represents the largest plasma-derived protein product by value. It is estimated that 70% of IVIG sold in the United States in 2007 was purchased by hospitals through contracts negotiated with GPOs. Physician offices represented about 13% of IGIV volume, and homecare companies and specialty pharmacies represented about 17% of IGIV volume.

49. There are no good substitutes for Ig.

50. Ig constitutes a relevant product market.

Albumin

51. Albumin is the most abundant protein in human plasma. It is synthesized by the liver and performs multiple functions, including the transport of many small molecules in the blood and the binding of toxins and heavy metals, which prevents damage that they otherwise might cause. Albumin is used to expand blood volume and to prime heart valves during surgery.

52. Albumin generally is used in surgical and trauma settings and typically is sold to hospital groups.

53. There are no good substitutes for albumin. Physicians and hospitals regard albumin as far superior from a clinical standpoint to any potential alternatives, such as hetastarch and saline products.

54. Albumin constitutes a relevant product market.

Relevant Geographic Market

55. The relevant geographic market is the United States.

56. Like pharmaceutical products, each Plasma-Derivative Protein Therapy must be approved for sale in the United States by the FDA. To obtain approval, the products must be

produced from plasma collected in the United States at collection centers approved by the FDA. The products also must be manufactured at plants approved by the FDA.

57. Performing the requisite clinical trials and undergoing the FDA approval process for plasma and plasma-derivative proteins, including Plasma-Derivative Protein Therapies, takes well over two years. Accordingly, Plasma-Derivative Protein Therapies sold outside of the United States are not viable competitive alternatives for United States customers, who cannot buy these products even in the event of a price increase for products available in the United States.

GOVERNMENT ANTITRUST INVESTIGATION

58. The FTC recently investigated the Plasma-Derivative Protein Therapies market and uncovered evidence suggesting the existence of an illegal price-fixing conspiracy.

59. The circumstances surrounding the FTC's investigation involved a potential acquisition of Talecris by CSL. Pursuant to an Agreement and Plan of Merger, dated August 12, 2008 ("Agreement"), CSL proposed to acquire all of the outstanding voting securities of Talecris in a transaction valued at $3.1 billion.

60. The proposed acquisition was reviewed for potential anticompetitive effects by the FTC.

61. After an extensive eight month investigation, which included the collection of testimony and declarations from 21 witnesses, on May 27, 2009, the FTC filed an administrative complaint ("Complaint") to block the proposed acquisition because it would violate Section 5 of the Federal Trade Commission Act, as amended, 1 U.S.C. § 45, by (1) making CSL the world's largest maker of blood plasma products; (2) substantially reducing competition in the U.S. market for Plasma-Derivative Protein Therapies, among other plasma-based products; (3) limiting industry supply of Plasma-Derivative Protein Therapies, among other plasma-based

products; and (4) causing increased prices for Plasma-Derivative Protein Therapies, among other plasma-based products.

62. As a result of its investigation, and as described more fully herein, the FTC found that Defendants controlled capacity and engaged in signaling – *i.e.*, the intentional sharing of competitive information for purposes of securing accommodating responses from competitors.

63. Baxter publicly supported the consolidation of its two competitors, stating that the merger would be "a positive stabilizing move within the industry," despite the fact that the merger would enhance CSL's competitive position relative to Baxter.

64. The FTC's complaint was heavily redacted at the demand of Talecris and CSL. In a motion to place the unredacted complaint on the public record, the FTC stated that the redacted "language suggests a strong possibility of ongoing coordinated interaction between firms in the plasma industry. Evidence of transparency, interdependence, and signaling among firms is particularly relevant to the allegations in this matter. The language at issue bears on these very important points, and demonstrates how firms used specific key words to:

- suggest to each other that increasing the production of lifesaving drugs could hurt the firms' ability to reap the significant profits they all achieved during an extended period where demand exceeded supply for the key products;
- remind each other of how, during a period when supply increased, prices and profitability for the firms in the market dropped significantly; and
- encourage each other to only increase supply incrementally to keep pace with demand, not increase supply to the extent the firms actually compete with each other for market share."

65. In the motion, the FTC also stated that the redacted language "is similar to language that in other instances has been found to be evidence supporting an illegal price fixing conspiracy," and relied on *In Re High Fructose Corn Syrup Antitrust Litigation,* 295 F.3d 651, 662 (7th Cir. 2002) (Posner, J.) (Mentioning an "understanding between the companies that ...

causes [them] not to ... make irrational decisions," and querying whether competitors will "play by the rules (discipline)," can be evidence of an explicit agreement to fix prices).

66. CSL has opposed the motion to lift the redactions in the FTC Complaint. The FTC has responded by stating that the redacted material does not qualify as confidential business information, and that while disclosure of the material may expose CSL to potential treble damages actions and cause it some embarrassment, those are insufficient reasons to prevent disclosure.

67. On June 8, 2009, less than two weeks after the FTC filed its Complaint, CSL and Talecris announced that they agreed to terminate their merger agreement. On June 15, 2009, the FTC and CSL filed a joint motion to dismiss the Complaint.

68. As the columnist Eli Greenblat wrote for the *Age*, an Australian news periodical: "Part of the official reason for pulling the takeover was that Talecris' private equity owners refused to give CSL more time beyond an August cut-off to seal the deal. They wanted their $US 75 million ($A 95 million) break fee and would not consider pushing back the deadline. If this is true, it must be one of the only private equity firms going that in this financial crisis prefers to run a business than have $US 3.1 billion cash in the bank." Further, "What use would it be [for CSL] to capture rival Talecris only to bring down the entire blood plasma industry on [its] head as the FTC handed to the US Department of Justice what it believed was a prima facie case of collusion and price fixing."

69. Since the takeover was not consummated, under the terms of the Agreement: (1) CSL must pay Talecris $75 million; and (2) CSL will supply Talecris with plasma for five years.

MASSIVE CONSOLIDATION IN THE INDUSTRY

70. In 1990, there were thirteen Plasma-Derivative Protein Therapy manufacturers; in 2003, there were nine. Today, there are only five: CSL, Talecris, Baxter, Grifols and Octapharma.

71. CSL and Baxter have used this massive industry consolidation as an opportunity to engage in unlawful anticompetitive conduct. Rather than increasing competition, the reduction in the number of Plasma-Derivative Protein Therapy manufacturers has increased coordination among competitors.

72. From the late 1990's through the early 2000's, Baxter acquired a number of biopharmaceutical companies. In 1997, Baxter acquired Immuno International AG, a global manufacturer of biopharmaceutical products and services for transfusion medicine. In 2001, Baxter acquired Sera-Tec Biologicals LP, which brought Baxter's number of plasma collection centers to 111 worldwide. In 2003, Baxter closed 26 plasma collection centers across the United States, as well as a plasma fractionation facility in Michigan. That same year, Baxter acquired Alpha Therapeutic Corporation, but sold more plasma collection centers that had been part of the acquisition.

73. Talecris was formed in March, 2005 when Cerberus Capital Management and Ampersand Ventures purchased the blood plasma division of Bayer. In 2008, Precision Pharma Services (a former Bayer-owned facility purchased by Ampersand Ventures in 2001) merged with Talecris.

74. In 2000, CSL acquired ZLB Blood Transfusion Service from the Swiss Red Cross and established ZLB Bioplasma. ZLB Plasma Services (now called CSL Plasma) was established in 2001, when CSL acquired 47 plasma collection centers and lab facilities in the United States. That same year, Aventis Behring acquired 42 plasma centers. In 2004, CSL

acquired Aventis Behring, combining it with ZLB Bioplasma to create ZLB Behring. Then, in 2006, ZLB Behring acquired CytoGam.

75. In 2005, the American Red Cross ("Red Cross") exited the business, and Baxter and the Red Cross agreed that the Red Cross would supply Baxter with plasma.

76. Richard Feinstein, Director of the FTC's Bureau of Competition, has stated that the substantial consolidation in the Plasma-Derivative Protein Therapies market, resulting in a highly concentrated market, has led to "troubling signs of coordinated behavior." Moreover, the FTC alleged that in its Complaint that if the proposed acquisition were approved, Defendants "would face no remaining significant obstacle in their efforts to coordinate and tighten supply conditions for the relevant products."

77. As alleged in the FTC Complaint, "the industry recognizes that controlling capacity is critical to preventing price competition and that consolidation has been an effective way to eliminate or control capacity. In fact, firms in the plasma industry have used consolidation as a tool to eliminate excess capacity and reduce supply, rather than produce benefits to consumers. CSL and Baxter each have reduced capacity following past acquisitions."

78. On April 22, 2004, Baxter announced that it would cut plasma production by 13% and close some of its plasma collection centers. This was followed less than a month later by CSL, when on May 11, 2004, it announced that it would close one-third of its blood collection centers in the U.S., just one month after it purchased the blood products business of Aventis, a former competitor. According to *Bloomberg News*, CSL's Managing Director, Brian McNamee, explained that by reducing the supply of blood products, CSL would gain more control over prices.

THE CONSPIRACY

79. In the early 2000s, Defendants' profits were steadily decreasing in the Plasma-Derivative Protein Therapies market. There were many players competing in the Plasma-Derivative Protein Therapies market, thus supply was ample and prices were falling. This was beneficial to consumers of Plasma-Derivative Protein Therapies.

80. This changed around 2004 after a period of massive industry consolidation, which resulted in a market characterized as a tight oligopoly and an opportunity for Defendants to turn the market around by concertedly manipulating output in order to raise prices.

81. Upon information and belief, Defendants devised a plan in which they could enhance profits from the sale of Plasma-Derivative Protein Therapies. Defendants agreed to fix, raise, maintain or stabilize prices of Plasma-Derivative Protein Therapies by restricting and/or controlling the output of such products. They successfully effectuated this unlawful scheme by, among other things, signaling their respective behaviors to each other and sharing proprietary information amongst themselves. By this conduct, Defendants artificially raised the prices of Plasma-Derivative Protein Therapies sold in the United States during the Class Period.

82. Defendants' scheme came to light following the FTC's investigation of the industry. According to the FTC, following the extensive consolidation in the industry, the few remaining participants "recognized that they are operating in an oligopoly in which they are better off avoiding competition, restricting supply, and raising prices."

83. The FTC further alleged in its Complaint that "the firms are keenly aware that restrained output is profitable only if all firms cooperate." In other words, it was not in Defendants' independent self-interest to restrain or restrict output – instead, it would be in their best economic interest to expand output in the face of increased demand in order to gain market share from their competitors.

84. Defendants encouraged one another to increase supply "incrementally to keep pace with demand," but no further. As a result, Defendants essentially refused to compete for incremental sales and thus increased market share.

85. The FTC Complaint stated that Baxter recognized that "as long as competitors are not 'irrational' and do not 'trash price and take share,' Baxter can increase supply steadily in line with market demand and keep prices high."

86. In order to communicate their unlawful scheme, the firms engaged in signaling – *i.e.*, the intentional sharing of competitive information for purposes of securing accommodating reactions from their competitors. The FTC found numerous examples of signaling among the Defendants.

87. Defendants used language at public events, among other places, that suggested the existence of an illegal price-fixing conspiracy. This language included "understanding" between companies, "irrational" decisions, "play by the rules," and "discipline."

88. Baxter's CFO acknowledged signaling in a recent investor call, stating:

> Why any of us would, for a very short-term gain, do anything to change [the current marketplace dynamics], I just don't see why we would. It wouldn't make sense and *from everything we read and all the signals we get, there is nothing that says anyone would do that. I think people are very consistent in the messages they deliver*, which are pretty consistent with what we have told you today.

89. On January 24, 2008, Baxter's CEO, Bob Parkinson, stated on a Q4 2007 earnings conference call that with respect to the plasma business, "it would seem that people [competitors] are doing what they need to do to ensure that the global demand can be met *collectively* by the industry."

90. In 2006, the Department of Health and Human Services ("HHS") investigated reports that patients were having problems obtaining Ig.

91. HHS went on to find that IGIV supplies were "being rationed" to such an extent that demand exceeded the supply of the drug by at least 14%.

92. The HHS Report also explained that "[m]anufacturers are currently allocating IGIV to their customers. Under this allocation system, most customers are expected to justify their current IGIV use to the manufacturer to maintain and/or increase their allocations."

93. Plasma-Derivative Protein Therapy manufacturers closely monitor each others' activities with respect to plasma collection, manufacturing and output.

94. CSL and Baxter have developed sophisticated oligopoly models to estimate and predict changes in supply and demand.

95. The FTC found that the Defendants are "collecting and cataloging an extraordinary wealth of timely competitive information, to ensure that all are engaging in desired … behavior."

96. Defendants also spoke publicly about their desire to raise prices.

97. On October 18, 2007, Baxter's CFO and Corporate Vice President, Rob Davis, stated on a Q3 2007 earnings conference call that with respect to Baxter's plasma business, there was going to be "price appreciation," and that Baxter expected to see "low to mid single digit price growth over our long-range horizon."

98. Defendants' scheme worked. As a result of their unlawful conspiracy, Defendants were able to raise prices for Plasma-Derivative Protein Therapies during the Class Period.

99. In a recent investor call, a Baxter executive explained that after competitors lived through the "events of the early 2000s" (referring to a period of ample supply and lower prices for Plasma-Derivative Protein Therapies), they have now returned to a time of "very good stock

prices and very good returns for shareholders," indicating the success of Defendants plan to increase prices by reducing supply.

100. Similarly, at the 2007 Plasma Protein Forum, held June 5-6 at the Hyatt Regency in Reston, Virginia, and attended by numerous industry executives, including those of Defendants, Peter Turner, PPTA Chairman and President of CSL Behring, "declared the industry to be in 'good shape' after a few bumps in the road in years past."

101. In addition, the HHS Report found that average prices for IGIV have been steadily increasing since 2004 and the upward trend was expected to continue through 2007. For example, in 2004 the average price for liquid IGIV was approximately $44 per gram, while for the first half of 2006, the price had risen to almost $48 a gram. By 2009, according to an analyst presentation by Grifols on March 5, 2008, the price for IVIG was projected to reach $57 a gram.

102. The average price of Albumin has increased from about $1.25 a gram in 2005 to about $2.20 a gram, according to the same Grifols presentation. The presentation also reports that "average albumin prices have steadily increased since 2005 from U.S. $14 to around U.S. $35 per 12.5 g. vial at present."

OTHER MARKET FACTORS SUPPORTING THE EXISTENCE OF THE CONSPIRACY

103. Various other factors make the market for Plasma-Derivative Protein Therapies particularly susceptible to an illegal conspiracy.

Highly Concentrated Industry

104. A high degree of concentration facilitates the operation of a price-fixing cartel because it makes it easier to coordinate behavior among co-conspirators, and it makes it more difficult for customers to avoid the effects of collusive behavior.

105. With respect to the domestic IVIG market, according to 2008 sales volumes, Defendants collectively possess a market share of approximately 62.9%. CSL possesses a market share of around 27.5%, and Baxter has a market share of around 35.4%. The remaining manufacturers, Talecris, Grifols, and Octapharma, possess shares of approximately 20.9%, 9%, and 7.2%, respectively.

106. With respect to the domestic albumin market, according to 2008 sales volumes, Defendants collectively possess a market share of approximately 73.05%. CSL has a market share of around 36.6%, and Baxter has a market share of around 36.44%. The remaining competitors, Talecris, Grifols, and Octapharma, possess shares of approximately 8.83%, 13.06%, and 5.07%, respectively.

107. At all relevant times during the Class Period, Defendants controlled the sales of Plasma-Derivative Protein Therapies in the United States. Both the Department of Health and Human Services and the FTC have described the Plasma-Derivative Protein Therapies market as "a tight oligopoly."

108. The Herfindahl-Hirschman Index ("HHI") is a widely-accepted measure of industry concentration that economists often use to quantify the degree of market concentration. HHI is calculated by summing the squares of companies' individual market shares within an industry. The U.S. Department of Justice ("DOJ") considers an HHI higher than 1800 to be a highly concentrated market.

109. The HHI for the Plasma-Derivative Protein Therapies market ranges from 2500 to over 3000, depending on the plasma product. This high HHI – well over 1800 – indicates that the Plasma-Derivative Protein Therapies market is extremely concentrated and is therefore highly susceptible to collusion.

Significant Entry Barriers

110. A collusive arrangement that raises product prices above competitive levels would, under normal circumstances, attract new entrants seeking to benefit from the supra-competitive pricing. Where, however, there are significant barriers to entry, new entrants are less likely. Thus, barriers to entry help to facilitate the operation of a cartel.

111. There are significant barriers to entry in the Plasma-Derivative Protein Therapy market. In its Complaint challenging the proposed CSL – Talecris merger, the FTC alleged that each step of the Plasma-Derivative Protein Therapy manufacturing process requires substantial up-front capital investment (sunk costs), "onerous and lengthy regulatory approvals", and specialized technical expertise.

112. According to the PPTA, "the development of new plasma-derived therapies is difficult and requires significant investment from manufacturers. Considerable research efforts and dedicated resources are required in new therapeutic areas to demonstrate clinical efficacy. In addition, development and validation of new production methods for these sensitive proteins is cumbersome and costly. Often the target patient groups are very small, often recognized as "orphan drug" populations, making patient recruitment into clinical trials slow and costly and the likely return on investment uncertain."

113. Furthermore, in their 2008 10-K, Baxter stated that their "investment in research and development is essential to its future growth and its ability to remain competitive in all three of its business segments." In 2008 alone, their investment in research and development activities was $868 million, up from $760 million in 2007.

114. Entry into the Plasma-Derivative Protein Therapies market also requires a significant amount of intellectual property, including trade secrets relating to purification and safety, and substantial product research and development. For example, "patents and other

proprietary rights are essential to Baxter's business. Baxter relies on trademarks, copyrights, trade secrets, know-how and confidentiality agreements to develop, maintain and strengthen its competitive position."

115. Entry into the Plasma-Derivative Protein Therapies market is also difficult because of the significant regulatory hurdles in getting products approved by the FDA. The FDA's regulatory requirements impose significant costs and considerable time to enter the market. The return on investment for most manufacturers takes a long time to realize, making entry into the market cost-prohibitive. For example, Baxter's facilities, operations, employees, products, and services face government regulation from a variety of agencies, including: the U.S. FDA, Drug Enforcement Agency, Environmental Protection Agency, Occupational Health and Safety Administration, Department of Agriculture, Department of Labor, Department of Defense, Customs and Border Protection, Department of Commerce, Department of the Treasury, as well as the Center for Medicare/Medicaid Services and the Office of the Inspector General within the Department of Health and Human Services. They are also subjected to regulation from state agencies and by international government agencies, who regulate public health, product registration, manufacturing, environmental conditions, labor, exports, imports, and other aspects of the company's global operations.

116. Because of these high barriers to entry, no new companies have entered the market *de novo* in recent history.

117. Similar barriers have precluded Talecris, Grifols, and Octapharma from significantly expanding production.

118. This market environment makes entry into the market or expansion from within unlikely to occur to a degree that is sufficient to counter the anticompetitive effects of the existing oligopoly.

Lack Of Reasonable Substitutes

119. The lack of available substitute products gives a potential cartel a greater chance of being successful. When few or no substitutes for a price-fixed item are available, producers of the item can raise a product's price and maintain it over time without losing significant sales. Consumers have little choice but to pay the higher price.

120. The product offerings of the Defendants are largely homogenous.

121. There are no substitutes for Ig available in the U.S. at any price.

122. There are no substitutes for Albumin available in the U.S. at any price. Physicians and hospitals regard Albumin as far superior from a clinical standpoint to any potential alternatives, such as hetastarch and saline products.

123. Plasma-derivative protein products sold outside of the U.S. are not viable alternatives for U.S. customers because the FDA requires that the plasma be U.S. plasma for FDA approval of the relevant drug therapies.

Standardized Product With High Degree Of Interchangeability

124. When products offered by different suppliers are viewed as interchangeable by purchasers, it is easier to unlawfully agree on the price for the product in question, and it is easier to effectively monitor agreed-upon prices. This makes it easier to form and sustain an unlawful cartel.

125. For example, according to CSL's 2005 Annual Report, it has "standardized operational systems across its US plasma collection centers and [it is] well advanced with developing a fully integrated global plasma supply chain that will further help [it] to manage

plasma inventory." The high level of industry regulation leads to a standardization of the products sold by market participants. In the same Annual Report, CSL also stated, "in a stringently regulated industry, [it complies] with the highest international standards and continue[s] to explore avenues for further innovation." Similarly, it stated in its 2007 Annual Report, "the largest collector of human blood plasma in the world, ZLB Plasma sources the plasma required by CSL Behring through its plasma collection operations and commercial purchases. In this stringently regulated industry, CSL Behring and ZLB Plasma meet or exceed international standards…"

126. Pricing and other variables for Plasma-Derivative Protein Therapies are standardized. The FTC claims this "enhance[s] the high degree of transparency in the industry."

127. Defendants' Ig Plasma-Derivative Protein Therapies are functional equivalents and essentially interchangeable.

128. Defendants' Albumin Plasma-Derivative Protein Therapies are functional equivalents and essentially interchangeable.

Nondurable Product

129. It is easier to cartelize a nondurable product market than a durable product market. In a durable market, buyers can store the product and a secondary market can operate against attempts to raise prices. Blood plasma-derived products are nondurable and can only be stored for a limited period of time. Indeed, "plasma products are as demanding as medicine gets. The proteins in the plasma that make up antibodies—and, thus, are the target of plasma processing—are fragile and easily denatured. Most important from a packaging standpoint, the cold chain must be preserved all the way from production to use."

130. Furthermore, "plasma-based medications are extremely sensitive to heat. If they are exposed to temperatures outside specified ranges at any point in the distribution chain, it can compromise their efficacy." According to the American Red Cross, the shelf life for [plasma] is only one year.

Many Buyers

131. There are numerous customers who purchase blood plasma-derived products. With many buyers, each of whom forms a small share of the marketplace, there is less incentive for cartel members to cheat on collusive pricing arrangements, since each potential sale is small while the risk of disrupting the collusive pricing agreement carries large penalties.

132. In their 2005 10-K, Baxter states that its products are used by "hospitals, clinical and medical research laboratories, blood and plasma collection centers, kidney dialysis centers, rehabilitation centers, nursing homes, doctors' offices, and by patients at home under physical supervision."

133. Baxter manufactures products in 28 countries and sells them in over 100.

134. Similarly, CSL Limited wrote in its 2007 Annual Report that it minimized "the credit risks associated with trade and other debtors by undertaking transactions with a large number of customers in various countries."

Opportunities for Meeting Competitors

135. Participation in trade associations can be used to foster and facilitate an unlawful conspiracy.

136. The PPTA is an industry self-regulatory body that serves as the global representative of the world's leading plasma collectors and producers of plasma-derived and recombinant biological therapeutics. Defendants are members of the PPTA, and thus have the opportunity to share information and conspire at meetings and events.

137. Defendants are Global and North American Members of the PPTA, and their high-level executives, including Peter Turner, President of CSL Behring, Larry Guiheen, President of Baxter BioScience serve on the PPTA's Global Board of Directors. Mr. Turner also serves as the PPTA's president.

138. In addition, the Global Management Committee of the PPTA comprises three members, including one from each Defendant; the North America Board of Directors of the PPTA comprises three members, including one from each Defendant; and the Source Board of Directors of the PPTA comprises three members, including one from each Defendant.

139. The PPTA convenes its annual meeting, known as the Plasma Protein Forum, in June in the Washington, D.C. metropolitan area, and high-level executives from Defendants regularly attend.

Record of Antitrust Inquiry

140. One of the factors that make the existence of a collusive pricing arrangement more likely is a record of antitrust inquiry. In May 2009, the Federal Trade Commission authorized a lawsuit to block CSL's proposed $3.1 billion merger with Talecris. As part of its investigation, the FTC noted that the market has exhibited, "troubling signs of coordinated behavior," and that Baxter and CSL had made "efforts to coordinate and tighten supply conditions" for Plasma-Derivative Protein Therapies.

ALLEGATIONS OF ANTITRUST INJURY TO PLAINTIFF AND THE CLASS

141. Defendants' unlawful conspiracy had and is having the following effects, among others:

(a) prices charged to Plaintiff and the Class for Plasma-Derivative Protein Therapies have been fixed, maintained, or stabilized at higher, artificially derived, non-competitive levels;

(b) Plaintiff and the Class have been deprived of the benefits of free, open and unrestricted competition in the sale of Plasma-Derivative Protein Therapies; and

(c) competition in establishing Plasma-Derivative Protein Therapies prices in the United States has been unlawfully restrained, suppressed and eliminated.

142. By reason of Defendants' violations of Section 1 of the Sherman Act and Section 4 of the Clayton Act, Plaintiff and the Class have sustained injury to their business or property. The injury sustained by Plaintiff and the Class is the payment of supra-competitive prices for Plasma-Derivative Protein Therapies. This is an injury of the type that the antitrust laws were meant to punish, prevent, and redress.

FRAUDULENT CONCEALMENT

143. Defendants fraudulently concealed their participation in the conspiracy alleged by, among other things, engaging in secret communications in furtherance of the conspiracy, and by holding themselves out as competitors to the public, to Plaintiff, and to the Class. Because of such fraudulent concealment, and the fact that a price-fixing conspiracy is inherently self-concealing, Plaintiff and the Class could not have discovered the existence of this conspiracy any earlier than its public disclosure by the FTC.

COUNT ONE

VIOLATIONS OF SECTION 1 OF THE SHERMAN ACT

144. Plaintiff incorporates by reference the preceding allegations.

145. Defendants and their unnamed co-conspirators entered into and engaged in a conspiracy in unreasonable restraint of trade in violation of Section 1 of the Sherman Act.

146. The conspiracy consisted of a continuing agreement, understanding or concerted action between and among Defendants and their co-conspirators to fix, maintain, raise and/or stabilize prices of Plasma-Derivative Protein Therapies in the United States by, among other

things, restricting or controlling output. Defendants' conspiracy is a *per se* violation of the federal antitrust laws and is, in any event, an unreasonable and unlawful restraint of trade.

147. As a proximate result of Defendants' unlawful conduct, Plaintiff and the Class have suffered injury in that they have paid supra-competitive prices for Plasma-Derivative Protein Therapies.

RELIEF SOUGHT

Accordingly, Plaintiff demands relief as follows:

A. That the Court determine that this action may be maintained as a class action under Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure, that Plaintiff be appointed as class representative, and that Plaintiff's counsel be appointed as counsel for the Class;

B. That the unlawful conspiracy alleged in Count I be adjudged and decreed to be an unreasonable restraint of trade or commerce, in violation of Section 1 of the Sherman Act;

C. That Plaintiff and the Class recover the damages determined to have been sustained as to each of them, trebled as provided by law, and that judgment be entered against Defendants, jointly and severally, on behalf of Plaintiff and each and every member of the Class;

D. That Plaintiff and the Class recover their costs of the suit, including attorney's fees, as provided by law; and

E. That the Court direct such further relief it may deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(a) of the Federal Rules of Civil Procedure, Plaintiff demands a jury trial as to all issues triable by a jury.

Dated: September 16, 2009

Respectfully submitted,

Eugene A. Spector
Jeffrey L. Kodroff
William G. Caldes
Jay S. Cohen
Jeffrey L. Spector
SPECTOR ROSEMAN KODROFF & WILLIS, P.C.
1818 Market Street, Suite 2500
Philadelphia, PA 19103
Telephone: 215-496-0300
Fax: 215-496-6611
espector@srkw-law.com
jkodroff@srkw-law.com
bcaldes@srkw-law.com
jcohen@srkw-law.com
jspector@srkw-law.com

John Murdock
Jeff Goldenberg
Theresa L.Groh
MURDOCK GOLDENBERG SCHNEIDER & GROH, L.P.A.
35 East Seventh Street, Suite 600
Cincinnati, Ohio 45202-2446
Telephone: 513-345-8291
Fax: 513-345-8294
jmurdock@mgsglaw.com
jgoldenberg@mgsglaw.com
tgroh@mgsglaw.com

Marc H. Edelson, Esq.
EDELSON & ASSOCIATES, L.L.C.
45 West Court Street
Doylestown, PA 18901
Telephone: 215-230-8043
Fax: 215-230-8735
medelson@edelson-law.com